

## **REMARKS**

In the Final Office Action mailed July 14, 2008, claims 1-30 and 35-37 were pending for consideration. All of the claims were rejected on various statutory grounds, each of which is addressed in turn below.

By the present amendment, claims 1, 2, 8, 22, 23, 35, and 37 have been amended.

Support for these amendments can be found in the specification as filed at paragraphs [0008]-[0010], [0031]-[0032], [0048], and FIG. 13. As such, the Applicant submits that no new matter is added thereby. Accordingly, claims 1-30 and 35-37 remain pending in the present application.

The Applicant respectfully submits that the present claims are allowable over the cited references.

### **Claim Rejections – 35 U.S.C. 112**

The Examiner has rejected claims 22-30 under 35 U.S.C. 112, first paragraph, as allegedly failing to comply with the written description requirement. Specifically, the Examiner has argued that claims 22 and 23 contain means plus function limitations without corresponding structural description. In order to move the prosecution of the application forward, claims 22 and 23 have been amended to remove the “means” language from the claim text. Reconsideration is respectfully requested.

### **Claim Rejections – 35 U.S. C. 102 - Vigh**

The Examiner has rejected claims 1, 3-4, 7-23, 25-30, and 35-37 under 35 U.S.C. 102(b) as being allegedly anticipated by U.S. Patent App. No. 2002/0043456 (hereinafter “Vigh”). Vigh teaches an electronic separation apparatus that utilizes isoelectric membranes to separate

components from a sample fluid (paragraphs [0013], [0014], [0015], [0024], [0026], [0037]). As is further described in paragraph [0037], an electric potential is applied to the apparatus to cause the migration of at least one selected component through at least one of the ion-permeable barriers. As such, Vigh is teaching the separation of analytes across an ion-permeable membrane.

The independent claims of the present application teach an isoelectric focusing method and apparatus for the separation of analytes without the use of a membrane. An electrical potential established between the present anode and cathode causes the establishment of a pH gradient within the separation chamber (paragraph [0032]). Analytes within the separation device are thus focused at points along the separation chamber based on the isoelectric potential of the analytes in the sample. The auxiliary agent(s) added to the device, either in the separation chamber or in auxiliary chambers, increases the concentration of the ampholytic sample components in the separation chamber, and thus improves the concentration detection limit of the isoelectric focusing system (paragraph [0008]).

The Applicant thus respectfully asserts that the Vigh reference does not teach each and every element of the independent claims of the present application. The analyte separation of the present claims does not occur across an ion-permeable membrane as is described by Vigh, but rather occurs along a pH gradient established in a separation chamber. Furthermore, Vigh does not teach or suggest the addition of an auxiliary chamber or an auxiliary agent to increase the concentration detection limit of an analyte in solution. Reconsideration is respectfully requested. Additionally, those claims that depend from the independent claims are narrower in scope, and it is also requested that these rejections be withdrawn as well.

## Claim Rejections – 35 U.S. C. 102 - Speicher

The Examiner has rejected claims 1, 7-24, 27, 29-30, and 35-37 under 35 U.S.C. 102(a) as being allegedly anticipated by U.S. Patent No. 6,638,408 (hereinafter “Speicher”). Speicher teaches a method and device for the separation of mixtures of charged molecules (col. 2, lines 50-52). Speicher further teaches an apparatus having a chamber for holding a liquid, and a series of membranes for separating analytes into a plurality of compartments (col. 2, lines 55-64; col. 4, line 57 to col. 5, line 6). As is described at col. 5, lines 55-59, the chamber is divided into separation compartments by porously charged membrane partitions. As is further described by Speicher, upon application of an electrical potential across the series of chambers, charged molecules migrate until entering a chamber where the molecule has a net charge of zero (col. 7, lines 40-46). Thus the molecules are separated by an electric field across charged porous membranes into individual compartments.

The Applicant respectfully asserts that Speicher does not teach or suggest each and every element of the present independent claims. Specifically, Speicher does not teach or suggest separating analytes along a pH gradient without the use of a separation membrane as is required by the present claims. Speicher also does not teach or suggest the use of auxiliary chambers and/or auxiliary agents to improve the concentration detection limit for an analyte in an isoelectric focusing system. Additionally, Speicher does not teach the isoelectric focusing of an analyte. While the term “isoelectric focusing” is used by Speicher in col. 4, lines 50-54 to describe that separation technique, the proper descriptive terminology should be “isoelectric trapping.” Isoelectric trapping describes numerous techniques for utilizing an isoelectric potential to trap an analyte on one side of a membrane. Such is the case with Speicher, where analytes are migrated along an isoelectric gradient to be trapped in a chamber surrounded by

charged membranes. Reconsideration is respectfully requested. Additionally, those claims that depend from the independent claims are narrower in scope, and it is also requested that these rejections be withdrawn as well.

#### **Claim Rejections – 35 U.S. C. 102 - Shave**

The Examiner has rejected claims 1-4, 7-15, 17, 20-23, 25-30, and 35-37 under 35 U.S.C. 102(a) as being allegedly anticipated by Shave et. al (hereinafter “Shave”). Shave teaches an isoelectric trapping system, which is described by the authors as a system whereby a target protein is trapped in an isoelectric state between two isoelectric membranes (col. 1, p. 381; col. 1, p. 382). As has been discussed above, the claims of the present application require that the separation of analytes occur by isoelectric focusing along a pH gradient in the absence of a separation membrane. Such isoelectric focusing is not taught or suggested by Shave, and therefore reconsideration is respectfully requested. Additionally, those claims that depend from the independent claims are narrower in scope, and it is also requested that these rejections be withdrawn as well.

#### **Claim Rejections – 35 U.S. C. 103 - Vigh**

The Examiner has rejected the following claims under 35 U.S.C. 103(a) as being allegedly unpatentable:

- claims 2, 5, 6, and 24 over Vigh;
- claims 3-4, 25-26, and 28 over Speicher in view of Pawliszyn;
- claims 5 and 6 over Speicher in view of Pawliszyn and Hofmann;
- claims 5, 6, 18-19, and 24 over Shave; and

claim 16 over Shave in view of Wu;

As has been discussed in the previous sections, Vigh, Speicher, and Shave, the primary references in all of the 103 rejections, teach separation systems that require a separation membrane to function. The present independent claims require, however, that analytes are separated along a pH gradient in the absence of a separation membrane. As such, the combinations of references do not teach or suggest all of the elements of the independent claims. Reconsideration is respectfully requested. Additionally, those claims that depend from the independent claims are narrower in scope, and it is also requested that these rejections be withdrawn as well.

### CONCLUSION

In view of the foregoing, the Applicant asserts that claims 1-30 and 35-37 of the present application present allowable subject matter and the allowance thereof is requested. If any impediment to the allowance of these claims remains after consideration of the present amendment and above remarks, and such impediment could be removed during a telephone interview, the Examiner is invited to telephone Todd Alder, or in his absence, Robert Mallinckrodt, so that such issues may be resolved as expeditiously as possible.

Please charge any additional fees except for Issue Fee or credit any overpayment to Deposit Account No. 20-0100.

Dated this 14<sup>th</sup> day of November, 2008.

Respectfully submitted,



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